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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

AMARIN PHARMA, INC. and AMARIN PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. HIKMA PHARMACEUTICALS USA INC., *et al.*, Defendants.	CASE NO.: 2:16-cv-02525-MMD-NJK (Consolidated with 2:16-cv-02562-MMD-NJK) **JOINT STIPULATIONS OF FACT**

I. INTRODUCTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, arising from Defendants'[1] filing of Abbreviated New Drug Applications ("ANDAs") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking approval from the United States Food and Drug Administration ("FDA") to market generic versions of Plaintiffs'[2] VASCEPA® product.

II. STIPULATED FACTS

For purposes of this case only, the parties stipulate to the following facts, which require no proof at trial:

A. THE PARTIES

2. Plaintiff Amarin Pharma, Inc. is a company organized and existing under the laws of Delaware with its principal place of business at 440 Route 22, Bridgewater, NJ 08807.

3. Plaintiff Amarin Pharmaceuticals Ireland Limited is a company incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

4. Defendant Hikma Pharmaceuticals USA Inc. is a company organized and existing under the laws of Delaware with its principal place of business at 246 Industrial Way West, Eatontown, NJ 07724.

[1] Defendants Hikma Pharmaceuticals USA Inc. and Hikma Pharmaceuticals International Limited (collectively, "Hikma") and Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL") (Hikma and DRL collectively, "Defendants").

[2] Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited (collectively, "Plaintiffs" or "Amarin").

5. Defendant Hikma Pharmaceuticals International Limited is a company incorporated under the laws of the United Kingdom with registered offices at 1 New Burlington Place, London, England W1S 2HR.

6. Defendant Dr. Reddy's Laboratories, Inc. is a company organized and existing under the laws of New Jersey with its principal place of business at 107 College Road East, Princeton, NJ 08540.

7. Defendant Dr. Reddy's Laboratories, Ltd. is an Indian public limited liability company organized and existing under the laws of India and having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 500 034, India.

B. THE ASSERTED PATENTS

8. Amarin Pharmaceuticals Ireland Limited is the owner of the Asserted Patents.[3]

9. Each of the Asserted Patents is entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA."

10. The U.S. Applications that ultimately issued as the Asserted Patents are continuations of U.S. Application No. 12/702,889, filed on February 9, 2010, which ultimately issued as U.S. Patent No. 8,293,727 ("the '727 Patent").

11. The Asserted Patents further claim priority to U.S. Provisional Application No. 61/151,291, filed on February 10, 2009, and U.S. Provisional Application No. 61/173,755, filed on April 29, 2009.

12. Mehar Manku, Ian Osterloh, Pierre Wicker, Rene Braeckman, and Paresh Soni are named as inventors of the Asserted Patents.

[3] U.S. Patent No. 8,293,728 ("the '728 Patent"), U.S. Patent No. 8,318,715 ("the '715 Patent"), U.S. Patent No. 8,357,677 ("the '677 Patent"), U.S. Patent No. 8,367,652 ("the '652 Patent"), U.S. Patent No. 8,431,560 ("the '560 Patent"), and U.S. Patent No. 8,518,929 ("the '929 Patent")

13. Pursuant to 21 U.S.C. § 355(b)(1), the Asserted Patents are listed in the Orange Book—published by FDA and formally known as *Approved Drug Products with Therapeutic Equivalence Evaluations*—in connection with New Drug Application ("NDA") No. 202057.

1. The '728 Patent

14. The PTO issued the '728 Patent on October 23, 2012.

15. Amarin Pharmaceuticals Ireland Limited filed U.S. Application No. 13/349,153, which ultimately issued as the '728 Patent, on January 12, 2012.

16. U.S. Application No. 13/349,153 is a continuation of U.S. Application No. 12/702,889, filed on February 9, 2010, now the '727 Patent.

2. The '715 Patent

17. The PTO issued the '715 Patent on November 27, 2012.

18. The PTO issued a Certificate of Correction to the '715 Patent on August 11, 2015.

19. The PTO issued a Certificate of Correction to the '715 Patent on May 21, 2019.

20. Amarin Pharmaceuticals Ireland Limited filed U.S. Application No. 13/282,145, which ultimately issued as the '715 Patent, on October 26, 2011.

21. U.S. Application No. 13/282,145 is a continuation of U.S. Application No. 12/702,889, filed on February 9, 2010, now the '727 Patent.

3. The '677 Patent

22. The PTO issued the '677 Patent on January 22, 2013.

23. Amarin Pharmaceuticals Ireland Limited filed U.S. Application No. 13/608,775, which ultimately issued as the '677 Patent, on September 10, 2012.

24. U.S. Application No. 13/608,775 is a continuation of U.S. Application No. 13/349,153, filed on January 12, 2012, now the '728 Patent, which is a continuation of U.S. Application No. 12/702,889, filed on February 9, 2010, now the '727 Patent.

4. The ’652 Patent

25. The PTO issued the ’652 Patent on February 5, 2013.

26. Amarin Pharmaceuticals Ireland Limited filed U.S. Application No. 13/610,247, which ultimately issued as the ’652 Patent, on September 11, 2012.

27. U.S. Application No. 13/610,247 is a continuation of U.S. Application No. 13/349,153, filed on January 12, 2012, now the ’728 Patent, which is a continuation of U.S. Application No. 12/702,889, filed on February 9, 2010, now the ’727 Patent.

5. The ’560 Patent

28. The PTO issued the ’560 Patent on April 30, 2013.

29. Amarin Pharmaceuticals Ireland Limited filed U.S. Application No. 13/711,329, which ultimately issued as the ’560 Patent, on December 11, 2012.

30. U.S. Application No. 13/711,329 is a continuation of U.S. Application No. 13/623,450, filed on September 20, 2012, now the ’920 Patent, which is a continuation of U.S. Application No. 13/349,153, filed on January 12, 2012, now the ’728 Patent, which is a continuation of U.S. Application No. 12/702,889, filed on February 9, 2010, now the ’727 Patent.

6. The ’929 Patent

31. The PTO issued the ’929 Patent on August 27, 2013.

32. Amarin Pharmaceuticals Ireland Limited filed U.S. Application No. 13/776,242, which ultimately issued as the ’929 Patent, on February 25, 2013.

33. U.S. Application No. 13/776,242 is a continuation of U.S. Application No. 13/711,329, filed on December 11, 2012, now the ’560 Patent, which is a continuation of U.S. Application No. 13/623,450, filed on September 20, 2012, now the ’920 Patent, which is a continuation of U.S. Application No. 13/349,153, filed on January 12, 2012, now the ’728 Patent, which is a continuation of U.S. Application No. 12/702,889, filed on February 9, 2010, now the ’727 Patent.

7. Prior-Art References

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35. Matsuzawa et al., *Effect of Long-Term Administration of Ethyl Icosapentate (MND-21) in Hyperlipidaemic Patients*, 7 J. Clin. Therapeutic & Medicines 1801–1816 (1991) ("Matsuzawa") was published in 1991 and is prior art to the Asserted Patents.

36. Takaku et al., *Study on the Efficacy and Safety of Ethyl Icosapentate (MND-21) in Treatment of Hyperlipidemia Based on a Long-Term Administration Test*, 7 J. Clin. Therapeutics & Medicine 191–213 (1991) ("Takaku") was published in 1991 and is prior art to the Asserted Patents.

37. Wojenski et al., *Eicosapentaenoic Acid Ethyl Ester as an Antithrombotic Agent: Comparison to an Extract of Fish Oil*, Biochim. Biophys. Acta., 1081(1):33–38 (1991) ("Wojenski") was published in 1991 and is prior art to the Asserted Patents.

38. Nozaki et al., *Effects of Purified Eicosapentaenoic Acid Ethyl Ester on Plasma Lipoproteins in Primary Hypercholesterolemia*, 62 Int'l J. Vitamin & Nutrition Res. 256–60 (1992) ("Nozaki") was published in 1992 and is prior art to the Asserted Patents.

39. Hayashi et al., *Decreases in Plasma Lipid Content and Thrombotic Activity by Ethyl Icosapentate Purified from Fish Oils*, 56(1) Curr. Therap. Res. 24–31 (1995) ("Hayashi") was published in 1995 and is prior art to the Asserted Patents.

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47. National Institutes of Health, National Heart, Lung, and Blood Institute, "Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III, Executive Summary," May 2001) ("ATP III Guidelines") was published in 2001 and is prior art to the Asserted Patents.

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52. Yokoyama et al., *Effects of eicosapentaenoic acid on cardiovascular events in Japanese patients with hypercholesterolemia: Rationale, design, and baseline characteristics of the Japan EPA Lipid Intervention Study (JELIS)*, 146 Am. Heart J. 613–20 (2003) ("Yokoyama 2003") was published in 2003 and is prior art to the Asserted Patents.

53. Omacor® Label (2004) ("Omacor 2004") was published in 2004 and is prior art to the Asserted Patents.

54. Maki et al., *Lipid responses to a dietary docosahexaenoic acid supplement in men and women with below average levels of high density lipoprotein cholesterol*, 24 J. Am. Col. Nutr. 189–99 (2005) ("Maki") was published in 2005 and is prior art to the Asserted Patents.

55. Geppert et al., *Microalgal Docosahexaenoic Acid Decreases Plasma Triacylglycerol in Normolipidaemic Vegetarians: A Randomized Trial*, 95 Brit. J. Nutrition 779–86 (2006) ("Geppert") was published in 2006 and is prior art to the Asserted Patents.

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57. Lovaza®, Physicians' Desk Reference 2699 (62d ed. 2007) ("Lovaza PDR") was published in 2007 and is prior art to the Asserted Patents.

58. Lovaza® Label 2007 ("Lovaza 2007") was published in 2007 and is prior art to the Asserted Patents.

59. Satoh et al., *Purified Eicosapentaenoic Acid Reduces Small Dense LDL, Remnant Lipoprotein Particles, and C-Reactive Protein in Metabolic Syndrome*, 30 Diabetes Care 144–146 (2007) ("Satoh") was published in 2007 and is prior art to the Asserted Patents.

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61. Yokoyama et al., *Effects of Eicosapentaenoic Acid on Major Coronary Events in Hypercholesterolaemic Patients (JELIS): a Randomized Open-Label, Blinded Endpoint Analysis*, 369 Lancet 1090–98 (2007) ("Yokoyama 2007") was published in 2007 and is prior art to the Asserted Patents.

62. WO 2007/142118 ("WO '118") was published on December 13, 2007 and is prior art to the Asserted Patents.

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64. American Heart Association, *Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report*, 106 Circulation 3143 (2002) was published in 2002 and is prior art to the Asserted Patents.

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68. McLennan et al., *The cardiovascular protective role of docosahexaenoic acid*, 300 European J. Pharmacology 83 (1996) was published in 1996 and is prior art to the Asserted Patents.

69. Bays et al., *Prescription Omega-3 Fatty Acids and Their Lipid Effects: Physiologic Mechanisms of Action and Clinical Implications*, 6 Expert Reviews Cardiovascular Therapy 391 (2008) was published in 2008 and is prior art to the Asserted Patents.

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72. Rambjor et al., *Eicosapentaenoic Acid Is Primarily Responsible for Hypotriglyceridemic Effect of Fish Oil in Humans*, 31 Lipids S-45 (1996) was published in 1996 and is prior art to the Asserted Patents.

73. Balk et al., *Effects of omega-3 fatty acids on serum markers of cardiovascular disease risk: A systematic review*, 189 Atherosclerosis 19 (2006) was published in 2006 and is prior art to the Asserted Patents.

74. Woodman, et al., *Docosahexaenoic acid but not eicosapentaenoic acid increases LDL particle size in treated hypertensive type 2 diabetic patients*, 26 Diabetes Care 253 (2003) was published in 2003 and is prior art to the Asserted Patents.

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79. Austin et al., *Hypertriglyceridemia as a Cardiovascular Risk Factor*, 81 Am. J. Cardiology 7B (1998) was published in 1998 and is prior art to the Asserted Patents.

80. Hooper et al., *Risks and Benefits of Omega 3 Fats for Mortality, Cardiovascular Disease, and Cancer: Systematic Review*, 332 BMJ 752 (2006) was published in 2006 and is prior art to the Asserted Patents.

81. Rader, *Lipid Disorders, in* Textbook of Cardiovascular Medicine 55 (Eric J. Topol ed., 3d ed. 2007) was published in 2007 and is prior art to the Asserted Patents.

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83. Hamazaki et al., *Docosahexaenoic Acid-Rich Fish Oil Does Not Affect Serum Lipid Concentrations of Normolipidemic Young Adults*, 126 The Journal of Nutrition 2784 (1996) was published in 1996 and is prior art to the Asserted Patents.

84. Conquer et al., *Supplementation with an Algae Source of Docosahexaenoic Acid Increases (n-3) Fatty Acid Status and Alters Selected Risk Factors for*

Heart Disease in Vegetarian Subjects, 126 The Journal of Nutrition 3032 (1996) was published in 1996 and is prior art to the Asserted Patents.

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89. Buckley et al., *Circulating triacylglycerol and apoE levels in response to EPA and docosahexaenoic acid supplementation in adult human subjects*, 92 British J. Nutrition 477(2004) was published in 2004 and is prior art to the Asserted Patents.

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99. Maitra et al., *Comparison of two assays for measuring LDL cholesterol*, 43 Clinical Chemistry 1040 (1997) was published in 1997 and is prior art to the Asserted Patents.

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104. LOPID® Physicians' Desk Reference 2554 (58th ed. 2004) was published in 2004 and is prior art to the Asserted Patents.

105. TRICOR® Label (2004) was published in 2004 and is prior art to the Asserted Patents.

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107. EP 0 273 708 A2 was issued on July 6, 1988 and is prior art to the Asserted Patents.

108. EP 0 277 747 was issued on August 10, 1988 and is prior art to the Asserted Patents.

109. EP 0 347 509 was issued on December 27, 1988 and is prior art to the Asserted Patents.

110. U.S. Patent No. 5,215,630 was issued on June 1, 1993 and is prior art to the Asserted Patents.

111. U.S. Patent No. 5,840,944 was issued on November 24, 1998 and is prior art to the Asserted Patents.

112. U.S. Patent No. 6,303,330 was issued on November 6, 2001 and is prior art to the Asserted Patents.

113. U.S. Patent No. 6,384,077 was issued on May 7, 2002 and is prior art to the Asserted Patents.

114. U.S. Patent No. 6,846,942 was issued on January 25, 2005 and is prior art to the Asserted Patents.

115. U.S. Patent Application Publication No. 2003/0104048 was published on June 5, 2003 and is prior art to the Asserted Patents.

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124. Pownall, et al., *Correlation of Serum Triglyceride and Its Reduction by ω-3 Fatty Acids with Lipid Transfer Activity and the Neutral Lipid Compositions of High-density and Low-density Lipoproteins*, ATHEROSCLROSIS (1998) was published in 1998 and is prior art to the Asserted Patents.

125. Theobald, et al., *LDL Cholesterol-raising Effect of Low-dose Docosahexaenoic Acid in Middle-aged Men and Women*, 79:4 CLINICAL NUTRITION 558-563 (2004) was published in 2004 and is prior art to the Asserted Patents.

126. Virani and Nambi, *The Role of Lipoprotein-associated Phospholipase A2 As a Marker for Atherosclerosis*, 9 CURRENT ATHEROSCLEROSIS REPORTS 97-103 (2007) was published in 2007 and is prior art to the Asserted Patents.

127. Sanders, *Triglyceride-Lowering Effect of Marine Polyunsaturates in Patients with Hypertriglyceridemia*, 5 ARTERIOSCLEROSIS 459-465 (1985) was published in 1985 and is prior art to the Asserted Patents.

C. PROSECUTION HISTORY

1. The ’727 Patent

128. On December 8, 2010, before the first office action in U.S. Application No. 12/702,889, Applicants submitted Preliminary Amendment A, amending then pending claims in the application.

129. On April 19, 2011, before the first office action in U.S. Application No. 12/702,889, Applicants submitted Preliminary Amendment B, amending then pending claims in the application.

130. On May 11, 2011, an interview between Applicants’ representative and the Examiner was conducted regarding U.S. Application No. 12/702,889.

131. Applicants submitted a Declaration by Harold Bays, M.D. dated May 18, 2011, to support U.S. Application No. 12/702,889.

132. Applicants submitted a Declaration by Howard Weintraub, M.D. dated May 26, 2011, to support U.S. Application No. 12/702,889.

133. In a June 20, 2011 Office Action, the Examiner rejected then pending claims of U.S. Application No. 12/702,889.

134. On June 23, 2011, Applicants submitted a Response to Office Action Dated June 20, 2011, making amendments to then pending claims U.S. Application No. 12/702,889 and arguments that the application should be allowed.

135. On August 18, 2011, the Examiner issued a Final Rejection of U.S. Application No. 12/702,889, maintaining the prior rejections of then pending claims.

136. On September 21, 2011, Applicants filed a Request for Continued Examination and Response to Office Action Dated August 18, 2011, making amendments to then pending claims in U.S. Application No. 12/702,889 and arguments that the application should be allowed.

137. Applicants submitted a Declaration by Howard Weintraub, M.D. dated September 19, 2011, to support U.S. Application No. 12/702,889.

138. On November 4, 2011, the Examiner issued a Non-Final Office Action rejecting then pending claims of U.S. Application No. 12/702,889.

139. On January 13, 2012, Applicants filed a Response to Non-Final Office Action Dated November 4, 2011, making amendments to then pending claims in U.S. Application No. 12/702,889 and arguments that the application should be allowed.

140. Applicants submitted a Declaration of Dr. Philip Lavin dated December 16, 2011, to support U.S. Application No. 12/702,889.

141. Applicants submitted a Declaration of Harold Bays, M.D. dated January 8, 2012, to support U.S. Application No. 12/702,889.

142. On March 2, 2012, the Examiner issued a Non-Final Office Action rejecting then pending claims of U.S. Application No. 12/702,889.

143. On April 24, 2012, an interview between Applicants' representative and the Examiner was conducted regarding U.S. Application No. 12/702,889.

144. On May 16, 2012, Applicants filed a Response to Non-Final Office Action Dated March 2, 2012, making amendments to then pending claims in U.S. Application No. 12/702,889 and arguments that the application should be allowed.

145. Applicants submitted a Declaration of Harold Bays, M.D. dated May 8, 2012, to support U.S. Application No. 12/702,889.

146. Applicants submitted a Declaration of Dr. Philip Lavin dated May 10, 2012, to support U.S. Application No. 12/702,889.

147. On September 6, 2012, the Examiner issued a Notice of Allowance of U.S. Application No. 12/702,889 accompanied by a Notice of Allowability which included an Examiner's Amendment and an Examiner's Statement of Reasons for Allowance.

2. <u>The '728 Patent</u>

148. On April 4, 2012, the Examiner issued a Non-Final Office Action rejecting then pending claims of U.S. Application No. 13/349,153.

149. On June 27, 2012, Applicants filed a Response to Non-Final Office Action Dated April 4, 2012, making amendments to then pending claims in U.S. Application No. 13/349,153 and arguments that the application should be allowed.

150. Applicants submitted a Declaration by Harold Bays, M.D. dated May 18, 2011, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/349,153.

151. Applicants submitted a Declaration of Harold Bays, M.D. dated June 26, 2012, to support U.S. Application No. 13/349,153.

152. Applicants submitted a Declaration of Dr. Philip Lavin dated December 16, 2011, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/349,153.

153. Applicants submitted a Declaration of Dr. Philip Lavin dated May 10, 2012, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/349,153.

154. Applicants submitted a Declaration by Howard Weintraub, M.D. dated May 26, 2011, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/349,153.

155. Applicants submitted a Declaration by Howard Weintraub, M.D. dated September 19, 2011, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/349,153.

156. On September 6, 2012, the Examiner issued a Notice of Allowance of U.S. Application No. 13/349,153 accompanied by a Notice of Allowability which included an Examiner's Statement of Reasons for Allowance.

3. <u>The '715 Patent</u>

157. On February 23, 2012, the Examiner issued a Non-Final Office Action rejecting then pending claims of U.S. Application No. 13/282,145.

158. On April 24, 2012, an interview between Applicants' representative and the Examiner was conducted regarding U.S. Application No. 13/282,145.

159. On May 16, 2012, Applicants filed a Response to Non-Final Office Action Dated February 23, 2012, making amendments to then pending claims in U.S. Application No. 13/282,145 and arguments that the application should be allowed.

160. Applicants submitted a Declaration of Dr. Philip Lavin dated December 16, 2011, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/282,145.

161. Applicants submitted a Declaration of Dr. Philip Lavin dated May 10, 2012, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/282,145.

162. Applicants submitted a Declaration of Harold Bays, M.D. dated January 8, 2012, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/282,145.

163. Applicants submitted a Declaration by Howard Weintraub, M.D. dated May 26, 2011, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/282,145.

164. Applicants submitted a Declaration by Howard Weintraub, M.D. dated September 19, 2011, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application 13/282,145.

165. On September 5, 2012, the Examiner issued a Notice of Allowance of U.S. Application No. 13/282,145 accompanied by a Notice of Allowability which included an Examiner's Statement of Reasons for Allowance.

4. The '677 Patent

166. On November 20, 2012, the Examiner issued a Notice of Allowance of U.S. Application No. 13/608,775 accompanied by a Notice of Allowability which included an Examiner's Statement of Reasons for Allowance.

5. The '652 Patent

167. On November 21, 2012, the Examiner issued a Notice of Allowance of U.S. Application No. 13/610,247 accompanied by a Notice of Allowability which included an Examiner's Statement of Reasons for Allowance.

6. The '560 Patent

168. On March 6, 2013, the Examiner issued a Notice of Allowance of U.S. Application No. 13/711,329 accompanied by a Notice of Allowability which included an Examiner's Statement of Reasons for Allowance.

7. The ’929 Patent

169. On May 13, 2013, the Examiner issued a Non-Final Office Action rejecting then pending claims of U.S. Application No. 13/776,242.

170. On May 17, 2013, Applicants filed an Amendment in Response to Non-Final Office Action, making amendments to then pending claims in U.S. Application No. 13/776,242 and arguments that the application should be allowed.

171. Applicants submitted a Declaration by Harold Bays, M.D. dated May 18, 2011, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/776,242.

172. Applicants submitted a Declaration of Harold Bays, M.D. dated June 26, 2012, originally filed in related U.S. Application No. 13/349,153, to support U.S. Application No. 13/776,242.

173. Applicants submitted a Declaration of Dr. Philip Lavin dated December 16, 2011, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/776,242.

174. Applicants submitted a Declaration of Dr. Philip Lavin dated May 10, 2012, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/776,242.

175. Applicants submitted a Declaration by Howard Weintraub, M.D. dated May 26, 2011, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/776,242.

176. Applicants submitted a Declaration by Howard Weintraub, M.D. dated September 19, 2011, originally filed in related U.S. Application No. 12/702,889, to support U.S. Application No. 13/776,242.

177. On June 19, 2013, the Examiner issued a Notice of Allowance of U.S. Application No. 13/776,242 accompanied by a Notice of Allowability which included an Examiner’s Statement of Reasons for Allowance.

D. DRUG APPLICATIONS

1. AMARIN'S NDA No. 202057

178. Amarin Pharmaceuticals Ireland Limited is the holder of NDA No. 202057.

179. Amarin Pharma, Inc. is Amarin Pharmaceuticals Ireland Limited's agent for purposes of communication with FDA regarding NDA No. 202057.

180. On July 26, 2012, FDA approved NDA No. 202057 for 1 g icosapent ethyl capsules. The approved indication was "as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia."

181. On February 16, 2017, FDA approved a supplement to NDA No. 202057 for 500 mg icosapent ethyl capsules.

182. Amarin Pharmaceuticals Ireland Limited and Amarin Pharma, Inc. market the 1 g and 500 mg strengths of the approved drug product under the tradename VASCEPA®.

2. HIKMA'S ANDA No. 209457

183. On or about July 26, 2016, Hikma Pharmaceuticals PLC and Roxane Laboratories, Inc., through Roxane Laboratories, Inc., submitted to FDA an ANDA (ANDA No. 209457) with paragraph IV certifications under Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to market a generic version of Vascepa® (icosapent ethyl) 1 g capsules as Icosapent Ethyl Capsules, 1 gram ("Hikma's ANDA Product").

184. On or about July 26, 2016, Hikma Pharmaceuticals PLC and Roxane Laboratories, Inc., through Roxane Laboratories, Inc., submitted to FDA a proposed labeling for Hikma's ANDA Product bearing revision date of "07/2016," *see, e.g.*, PX 103.

185. Pursuant to 21 U.S.C. § 355(j)(2)(B), in a letter dated September 21, 2016, Hikma Pharmaceuticals PLC and Roxane Laboratories, Inc. notified Amarin that they had submitted to FDA ANDA No. 209457, with paragraph IV certifications for the Asserted Patents.

186. On or about December 8, 2016, Roxane Laboratories, Inc. transferred ANDA No. 209457 to West-Ward Pharmaceuticals International Limited.

187. On or about December 8, 2016, West-Ward Pharmaceuticals International Limited appointed West-Ward Pharmaceuticals Corp. as its agent for purposes of communication with FDA regarding ANDA No. 209457.

188. On or about January 10, 2017, West-Ward Pharmaceuticals International Limited, through West-Ward Pharmaceuticals Corp., submitted to FDA a revised proposed labeling for Hikma's ANDA Product bearing revision date of "12/2016," *see, e.g.*, PX 274; DX 1700.

189. West-Ward Pharmaceuticals International Limited has changed its name to Hikma Pharmaceuticals International Limited.

190. West-Ward Pharmaceuticals Corp. has changed its name to Hikma Pharmaceuticals USA Inc.

191. On or about July 8, 2019, Hikma Pharmaceuticals International Limited transferred ANDA No. 209457 to Hikma Pharmaceuticals USA Inc. Hikma Pharmaceuticals USA Inc. is now the owner of ANDA No. 209457.

192. On or about December 30, 2019, Hikma Pharmaceuticals USA Inc. submitted to FDA a revised proposed labeling for Hikma's ANDA Product bearing revision date of "12/2019," PX 1203; DX 2256.

3. DRL'S ANDA No. 209499

193. On or about July 26, 2016, DRL, through Dr. Reddy's Laboratories, Inc., submitted to FDA an ANDA (ANDA No. 209499) with paragraph IV certifications under Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to market a generic version of Vascepa® (icosapent ethyl) 1 g capsules as Icosapent Ethyl Capsules, 1 gram ("DRL's ANDA Product").

194. On or about July 26, 2016, DRL, through Dr. Reddy's Laboratories, Inc., submitted to FDA a proposed labeling for DRL's ANDA Product bearing revision date of "06/2016," *see, e.g.*, PX 69.

195. Pursuant to 21 U.S.C. § 355(j)(2)(B), in a letter dated September 22, 2016, DRL notified Amarin that it had submitted to FDA ANDA No. 209499, with paragraph IV certifications for the Asserted Patents.

196. On or about January 4, 2017, DRL, through Dr. Reddy's Laboratories, Inc., submitted to FDA a revised proposed labeling for DRL's ANDA Product bearing revision date of "01/2017," *see, e.g.*, PX 207.

197. On or about July 11, 2018, DRL, through Dr. Reddy's Laboratories, Inc., submitted to FDA a supplement to ANDA No. 209499 with paragraph IV certifications under Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for 500 mg icosapent ethyl capsules purportedly bioequivalent to VASCEPA®.

198. Pursuant to 21 U.S.C. § 355(j)(2)(B), in a letter dated July 11, 2018, DRL notified Amarin that it had submitted to FDA a supplement to ANDA No. 20499, with paragraph IV certifications for the '728, '715, '677, '652, and '929 patents.

199. On or about July 23, 2018, DRL, through Dr. Reddy's Laboratories, Inc., submitted to FDA a revised proposed labeling for DRL's ANDA Product bearing revision date of "04/2018," *see, e.g.*, PX 574.

E. DRUG PRODUCTS

1. VASCEPA®

200. VASCEPA® is indicated "as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia."

201. The dosage form for VASCEPA® 1-gram capsules is a "1-gram amber-colored, oblong, soft-gelatin capsule."

202. The daily dose of VASCEPA® 1-gram capsules is "4 grams per day taken as . . . two 1-gram capsules twice daily with food."

203. The active pharmaceutical ingredient in VASCEPA® is icosapent ethyl, which is the ethyl ester of the omega-3 fatty acid, eicosapentaenoic acid ("EPA"). The terms

EPA, EPA-E, eicosapentaenoic acid, icosapent ethyl, ethyl-EPA, eicosapentaenoic acid ethyl ester, ethyl eicosapentaenoate, and ethyl eicosapent are used interchangeably in this case.

204. VASCEPA® contains a "pharmaceutical composition," as required by Claims 1 and 16 of the '728 Patent, Claim 14 of the '715 Patent, Claims 1 and 8 of the '677 Patent, Claim 1 of the '652 Patent, and Claims 1 and 5 of the '929 Patent.

205. The "pharmaceutical composition" in VASCEPA® comprises "at least about 96%, by weight of all fatty acids present, ethyl eicosapentaenoate[,] and substantially no docosahexaenoic acid or its esters," as required by Claims 1 and 16 of the '728 Patent, Claims 1 and 8 of the '677 Patent, and Claims 1 and 8 of the '652 Patent.

206. VASCEPA® contains a "pharmaceutical composition" "wherein no fatty acid of the pharmaceutical composition, except for ethyl-EPA, comprises more than about 0.6% by weight of all fatty acids combined," as required by Claim 16 of the '728 Patent.

207. The "pharmaceutical composition" in VASCEPA® comprises "at least about 96% by weight, ethyl eicosapentaenoate (ethyl-EPA) and substantially no docosahexaenoic acid (DHA) or its esters," as required by Claim 14 of the '715 Patent.

208. VASCEPA® comprises a "capsule comprising about 900 mg to about 1 g of ethyl eicosapentaenoate and not more than about 3% docosahexaenoic acid or its esters, by weight of total fatty acids present," as required by Claims 4 and 17 of the '560 Patent.

209. The "pharmaceutical composition" in a daily dose of VASCEPA® comprises "about 4 g of ethyl eicosapentaenoate and not more than about 4% docosahexaenoic acid or its esters, by weight of all fatty acids," as required by Claims 1 and 5 of the '929 Patent.

2. HIKMA'S ANDA PRODUCT

210. VASCEPA® is the Reference Listed Drug ("RLD") for ANDA No. 209457.

211. Hikma's ANDA Product, if approved, will be bioequivalent to VASCEPA®.

212. The indication set forth in the proposed labeling for Hikma's ANDA Product, submitted in connection with ANDA No. 209457, is "as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia."

213. The dosage form of Hikma's ANDA Product, if approved, will be a 1-gram soft-gelatin capsule.

214. The daily dose of Hikma's ANDA Product, if approved, will be 4 grams per day taken as two 1-gram capsules twice daily with food.

215. Hikma's ANDA Product, if approved, will contain icosapent ethyl.

216. Hikma's ANDA Product, if approved, will contain a "pharmaceutical composition," as required by Claims 1 and 16 of the '728 Patent, Claim 14 of the '715 Patent, Claims 1 and 8 of the '677 Patent, Claim 1 of the '652 Patent, and Claims 1 and 5 of the '929 Patent.

217. The "pharmaceutical composition" in Hikma's ANDA Product, if approved, will comprise "at least about 96%, by weight of all fatty acids present, ethyl eicosapentaenoate[,] and substantially no docosahexaenoic acid or its esters," as required by Claims 1 and 16 of the '728 Patent, Claims 1 and 8 of the '677 Patent, and Claim 1 of the '652 Patent.

218. Hikma's ANDA Product, if approved, will contain a "pharmaceutical composition" "wherein no fatty acid of the pharmaceutical composition, except for ethyl-EPA, comprises more than about 0.6% by weight of all fatty acids combined," as required by Claim 16 of the '728 Patent.

219. The "pharmaceutical composition" in Hikma's ANDA Product, if approved, will comprise "at least about 96% by weight, ethyl eicosapentaenoate (ethyl-EPA) and substantially no docosahexaenoic acid (DHA) or its esters," as required by Claim 14 of the '715 Patent.

220. Hikma's ANDA Product, if approved, will comprise a "capsule comprising about 900 mg to about 1 g of ethyl eicosapentaenoate and not more than about 3%

docosahexaenoic acid or its esters, by weight of total fatty acids present," as required by Claims 4 and 17 of the '560 Patent.

221. The "pharmaceutical composition" in a daily dose of Hikma's ANDA Product, if approved, will comprise "about 4 g of ethyl eicosapentaenoate and not more than about 4% docosahexaenoic acid or its esters, by weight of all fatty acids," as required by Claims 1 and 5 of the '929 Patent.

3. DRL's ANDA PRODUCT

222. VASCEPA® is the RLD for ANDA No. 209499.

223. DRL's ANDA Product, if approved, will be bioequivalent to VASCEPA®.

224. The indication set forth in the proposed labeling for DRL's ANDA Product, submitted in connection with ANDA No. 209499, is "as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia."

225. The dosage form of DRL's ANDA Product, if approved, will be a 1-gram soft-gelatin capsule.

226. The daily dose of DRL's ANDA Product, if approved, will be 4 grams per day taken as two 1-gram capsules twice daily with food.

227. DRL's ANDA Product, if approved, will contain icosapent ethyl.

228. DRL's ANDA Product, if approved, will contain a "pharmaceutical composition," as required by Claims 1 and 16 of the '728 Patent, Claim 14 of the '715 Patent, Claims 1 and 8 of the '677 Patent, Claim 1 of the '652 Patent, and Claims 1 and 5 of the '929 Patent.

229. The "pharmaceutical composition" in DRL's ANDA Product, if approved, will comprise "at least about 96%, by weight of all fatty acids present, ethyl eicosapentaenoate[,] and substantially no docosahexaenoic acid or its esters," as required by Claims 1 and 16 of the '728 Patent, Claims 1 and 8 of the '677 Patent, and Claim 1 of the '652 Patent.

230. DRL's ANDA Product, if approved, will contain a "pharmaceutical composition" "wherein no fatty acid of the pharmaceutical composition, except for ethyl-EPA,

comprises more than about 0.6% by weight of all fatty acids combined," as required by Claim 16 of the '728 Patent.

231. The "pharmaceutical composition" in DRL's ANDA Product, if approved, will comprise "at least about 96% by weight, ethyl eicosapentaenoate (ethyl-EPA) and substantially no docosahexaenoic acid (DHA) or its esters," as required by Claim 14 of the '715 Patent.

232. DRL's ANDA Product, if approved, will comprise a capsule comprising 950 mg to 1050 mg of ethyl eicosapentaenoate. DRL will not assert the claim limitation from Claims 4 and 17 of the '560 Patent that recites a "capsule comprising about 900 mg to about 1 g of ethyl eicosapentaenoate" as a basis for noninfringement of Claims 4 and 17 of the '560 Patent.

233. DRL's ANDA Product, if approved, will comprise "a capsule comprising . . . not more than about 3% docosahexaenoic acid or its esters, by weight of total fatty acids present," as required by Claims 4 and 17 of the '560 Patent.

234. The "pharmaceutical composition" in a daily dose of DRL's ANDA Product, if approved, will comprise "about 4 g of ethyl eicosapentaenoate and not more than about 4% docosahexaenoic acid or its esters, by weight of all fatty acids," as required by Claims 1 and 5 of the '929 Patent.

DATED: January 6, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 6, 2020, I caused true and correct copy of **JOINT STIPULATIONS OF FACT** to be filed with the Clerk of the Court using the Court's CM/ECF system, and service was thereby effected electronically on the following counsel of record in this matter:

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